

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claims 1-44 (cancelled)

Claim 45 (currently amended): A device for determining the concentration of an analyte in a biological fluid from a patient, comprising:

a piercing member sufficient to cause the fluid to flow from a site on the patient;

a sensor sufficient to generate an electrical signal indicative of the concentration of the analyte in the fluid, the sensor comprising: a working electrode; a sensing layer; a counter electrode; and a measurement zone sized to contain a volume of less than about 1 μ l; and

an analyzer operatively connected to the sensor, and

wherein the piercing member and the sensor are mechanically attached together to form an integrated unit that is disconnectable from said analyzer as said integrated unit.

Claim 46 (previously presented): The device of claim 45, wherein the piercing member is a lancet.

Claim 47 (currently amended): The device of claim 45, wherein the sensing layer comprises at least one agent sufficient for transferring electrons ~~electrodes~~ between the working electrode and analyte.

Claim 48 (previously presented): The device of claim 47, wherein the at least one agent comprises a redox mediator and/or an enzyme.

Claim 49 (previously presented): The device of claim 47, wherein the at least one agent comprises an enzyme selected from a lactase oxidase, a glucose oxidase, and a glucose dehydrogenase.

Claim 50 (previously presented): The device of claim 45, wherein the measurement zone is sized to contain a volume of less than about 0.5 μl .

Claim 51 (previously presented): The device of claim 45, wherein the sensor comprises a strip.

Claim 52 (previously presented): The device of claim 45, wherein the working electrode is on a first substrate and the counter electrode is on a second substrate.

Claim 53 (previously presented): The device of claim 45, wherein the working electrode and the counter electrode are coplanar.

Claim 54 (previously presented): The device of claim 45, wherein the sensor further comprises a third electrode.

Claim 55 (previously presented): The device of claim 45, the sensor being such that the signal generated by the sensor in connection with electrolysis of a buffer solution having a 10 mM concentration of the analyte is at least about nine times greater than the signal generated by the sensor in connection with electrolysis of the buffer solution absent the analyte.

Claim 56 (Previously presented): The device of claim 45, further comprising a sorbent material for transporting the fluid from the site to the sensor.

Claim 57 (currently amended): The device of claim 56, wherein at least a portion of the sorbent material is disposed ~~deposed~~ in the measurement zone.

Claim 58 (previously presented): The device of claim 45, further comprising means for transporting the fluid from the site to the sensor.

Claim 59 (previously presented): The device of claim 58, wherein the means for transporting comprises vacuum-producing means.

Claim 60 (currently amended): The device of claim 58, wherein the means for transporting comprises pressure application, vacuum creation, capillary action, or ~~and/or~~ wicking action, or combinations thereof.

Claim 61 (previously presented): The device of claim 45, wherein the analyzer comprises an amperometric analyzer.

Claim 62 (previously presented): The device of claim 45, wherein the analyzer comprises a coulometric analyzer.

Claim 63 (currently amended): The device of claim 45, wherein the fluid comprises ~~is selected from~~ blood, interstitial fluid, dermal fluid, sweat, or ~~and~~ tears, or combinations thereof.

Claim 64 (previously presented): The device of claim 45, wherein the analyte is selected from lactate and glucose.

Claim 65 (previously presented): The device of claim 45, wherein the piercing member, the sensor, and the analyzer form an integrated unit.

Claim 66 (previously presented): The device of claim 65, wherein the sensor is detachable from the integrated unit.

Claim 67 (currently amended): The device for determining a concentration of an analyte in a fluid from a site on a subject, comprising:

a piercing member sufficient to pierce the site such that the fluid flows therefrom; and

a sensor sufficient to generate a signal indicative of the concentration of the analyte in the fluid, the sensor comprising: a working electrode; a sensing layer; a counter electrode; and a measurement zone size to contain a volume of less than about 1 μ l;

wherein the sensor is adapted so that a signal generated by the sensor in connection with electrolysis of a buffer solution with 10 mM glucose is greater than a signal generated by the sensor in connection with electrolysis of a buffer solution with no glucose, and

wherein the piercing member and the sensor are mechanically attached together to form an integrated unit that is disconnectable from said analyzer as said integrated unit.

Claim 68 (previously presented): The device of claim 67, wherein the sensor is adapted so that a signal generated by the sensor in connection with electrolysis of a buffer solution with 10 mM glucose is about nine times greater than a signal generated by the sensor in connection with electrolysis of a buffer solution with no glucose.

Claim 69 (previously presented): The device of claim 67, further comprising an analyzer operatively associated with the sensor.

Claim 70 (currently amended): A method for determining the concentration of an analyte in a fluid from a site on a subject, the method comprising:

providing a piercing member, a sensor for generating a signal, and an analyzer for measuring the signal, wherein the sensor comprises: a working electrode; a sensing layer; a counter electrode; and a measurement zone, and wherein the piercing member and the sensor are mechanically attached together to form an integrated unit that is disconnectable from said analyzer as said integrated unit;

piercing the site via the piercing member such that fluid flows from the site to the measurement zone;

generating a signal indicative of the concentration of the analyte in the fluid using less than about 1 μ l of the fluid in the measurement zone via the sensor, ~~and~~

measuring the signal via the analyzer; and
disconnecting said integrated unit from said analyzer.

Claim 71 (previously presented): The method of claim 70, wherein the piercing member comprises a lancet.

Claim 72 (previously presented): The method of claim 70, wherein the sensing layer comprises at least one agent sufficient for transferring electrons between the working electrode and the analyte.

Claim 73 (currently amended): The method of claim 72, wherein the at least one agent comprises a redox mediator or ~~and/or~~ an enzyme or both.

Claim 74 (currently amended): The method of claim 72, wherein the at least one agent comprises an enzyme comprising ~~selected from~~ a lactase, a glucose oxidase, and a glucose dehydrogenase or combinations thereof.

Claim 75 (previously presented): The method of claim 70, wherein the signal is generated using no more than about 0.5 μ l of the fluid in the measurement zone.

Claim 76 (previously presented): The method of claim 70, wherein the working electrode is on a first substrate and the counter electrode is on a second substrate.

Claim 77 (previously presented): The method of claim 70, wherein the sensor further comprises a third electrode.

Claim 78 (previously presented): The method of claim 70, the sensor being such that the signal generated by the sensor in connection with electrolysis of a buffer solution having a 10 mM concentration of the analyte is at least about nine times greater than the signal generated by the sensor in connection with electrolysis of a buffer solution absent the analyte.

Claim 79 (previously presented): The method of claim 70, further comprising transporting the fluid from the site to the measurement zone via a sorbent material.

Claim 80 (previously presented): The method of claim 79, wherein at least a portion of the sorbent material is disposed in the measurement zone.

Claim 81 (currently amended): The method of claim 70, further comprising, before said measuring, providing a vacuum at or around the site.

Claim 82 (currently amended): The method of claim 70, further comprising transporting the fluid from the site to the measurement zone via vacuum, pressure, capillary action, or and/or wicking action, or combinations thereof.

Claim 83 (previously presented): The method of claim 70, wherein said measuring comprises amperometrically measuring.

Claim 84 (previously presented): The method of claim 70, wherein said measuring comprises coulometrically measuring.

Claim 85 (currently amended): The method of claim 70, wherein the fluid comprises ~~is selected from~~ blood, interstitial fluid, dermal fluid, sweat, or and tears, or combinations thereof.

Claim 86 (currently amended): The method of claim 70, wherein the analyte comprises ~~is selected from~~ lactate or and glucose or both.

Claim 87 (previously presented): The method of claim 70, wherein the site is located on an arm of the subject.

Claim 88 (previously presented): The method of claim 70, wherein the piercing member, the sensor, and the analyzer form an integrated unit.

Claim 89 (new): The device of claim 45, wherein said integrated unit is configured for both lancing and sensing when said piercing member and sensor are attached together as said integrated unit.

Claim 90 (new): The device of claim 45, wherein said integrated unit is configured for connecting said sensor to said analyzer as said integrated unit.

Claim 91 (new): The device of claim 90, wherein the working electrode is configured for connecting with the analyzer which provides an electrical potential causing an electrochemical reaction within the fluid that is applied to the measurement zone and performs electrochemical analysis of said fluid and thereby determines said concentration of said analyte, and wherein said integrated unit is configured for connecting to said analyzer for obtaining said electrochemical analysis and analyte concentration determination.

Claim 92 (new): The device of claim 90, wherein said integrated unit is configured for separating and disposing as an integrated unit from said analyzer after said analysis and determination.

Claim 93 (new): The device of claim 90, wherein said integrated unit is configured for both lancing and sensing when said piercing member and sensor are attached together as said integrated unit.

Claim 94 (new): The device of claim 45, wherein said integrated unit is configured for separating and disposing as an integrated unit from said analyzer after said analysis and determination.

Claim 95 (new): The device of claim 94, wherein said integrated unit is configured for both lancing and sensing when said piercing member and sensor are attached together as said integrated unit.

Claim 96 (new): The device of claim 67, wherein said integrated unit is configured for both lancing and sensing when said piercing member and sensor are attached together as said integrated unit.

Claim 97 (new): The device of claim 67, wherein said integrated unit is configured for connecting said sensor to said analyzer as said integrated unit.

Claim 98 (new): The device of claim 97, wherein the working electrode is configured for connecting with the analyzer which provides an electrical potential causing an electrochemical reaction within the fluid that is applied to the measurement zone and performs electrochemical analysis of said fluid and thereby determines said concentration of said analyte, and wherein said integrated unit is configured for connecting to said analyzer for obtaining said electrochemical analysis and analyte concentration determination.

Claim 99 (new): The device of claim 97, wherein said integrated unit is configured for separating and disposing as an integrated unit from said analyzer after said analysis and determination.

Claim 100 (new): The device of claim 97, wherein said integrated unit is configured for both lancing and sensing when said piercing member and sensor are attached together as said integrated unit.

Claim 101 (new): The device of claim 67, wherein said integrated unit is configured for separating and disposing as an integrated unit from said analyzer after said analysis and determination.

Claim 102 (new): The device of claim 101, wherein said integrated unit is configured for both lancing and sensing when said piercing member and sensor are attached together as said integrated unit.

Claim 103 (new): The method of claim 70, wherein said piercing, generating and measuring occur when said piercing member and sensor are attached together as said integrated unit.

Claim 104 (new): The method of claim 70, further comprising connecting said sensor to said analyzer when said piercing member and sensor are attached together as said integrated unit.

Claim 105 (new): The method of claim 104, further comprising connecting the working electrode to the analyzer which provides an electrical potential causing an electrochemical reaction within the fluid that is applied to the measurement zone and performs electrochemical analysis of said fluid and thereby determines said concentration of said analyte.

Claim 106 (new): The method of claim 104, further comprising separating and disposing said integrated unit from said analyzer after said analysis and determination.

Claim 107 (new): The method of claim 104, wherein said piercing, generating and measuring occur when said piercing member and sensor are attached together as said integrated unit.

Claim 108 (new): The method of claim 70, further comprising separating and disposing said integrated unit from said analyzer after said analysis and determination.

Claim 109 (new): The method of claim 108, wherein said piercing, generating and measuring occur when said piercing member and sensor are attached together as said integrated unit.